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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,653	03/18/2004	John McCafferty	05569.0004.DVUS12	8022

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EXAMINER	
STEELE, AMBER D	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/803,653	MCCAFFERTY ET AL.	
	Examiner	Art Unit	
	Amber D. Steele	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-5 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-5 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 10/18/04; 10/26/04; 3/18/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-5 are currently pending and under consideration.

Information Disclosure Statement

2. The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a). Therefore, unless the references cited in the international search report cited in the IDS received on October 18, 2004 were submitted the references were not considered.

3. The information disclosure statements filed March 18, 2006 and October 28, 2006 fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Please note that applications 08/484,893 and 07/971,857 were ordered by the examiner to check for references cited in the IDS. However, the cases were removed prior to examination and are currently not available for review.

Drawings

4. The drawings/figures are objected to because tables and sequence listings included in the specification must not be duplicated in the drawings. See 37 CFR §1.58(a) and §1.83(a). Applicants are advised that upon issuance of a patent, the complete text of the sequence listing submitted in compliance with 37 CFR §§1.821-1.825 will be published as part of the patent. Applicants should amend the specification to delete any figures/drawings which consist only of nucleic acid or protein sequences which have been submitted in their entirety in computer readable format (e.g. as SEQ ID Nos) and should further amend the specification accordingly to reflect the replacement of the drawing/figure by the appropriate SEQ ID NO. Alternatively, if the drawing provides additional information not provided by the sequences listing (e.g. alignments, structure, etc.) then the drawing may remain. However, an appropriate SEQ ID NO: is required for each sequence.

Appropriate correction is required.

Specification

5. The abstract of the disclosure is objected to because it contains more than 150 words. (See MPEP § 608.01, Abstract of the Disclosure: A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims).

Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited.

6. The disclosure is objected to because of the following informalities: sequences are present without a corresponding SEQ ID NO: (for examples see page 259) and □ symbols are present throughout the specification (for examples see pages 228-230; assumed to be °C, but must be corrected).

Appropriate correction is required.

7. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications under the 35 USC 112, first paragraph "Written Description" requirement, Federal Register, Vol. 66, No. 4 pages 1099-1111, Friday January 5, 2001. This is a **written description** rejection.

Claim 1 is drawn to a method for producing a binding molecule specific for a particular target comprising producing a population of filamentous bacteriophage particles surface displaying a population of binding molecules wherein the bacteriophage contains nucleic acid and selecting for a filamentous bacteriophage displaying a binding molecule that binds a target. The invention as claimed encompasses all known and all potential binding molecules, targets, filamentous bacteriophage, and nucleic acid containing signaling sequences which can express proteins on the surface since virtually any molecule can be bound with a certain affinity (e.g. even non-specifically) by a particular target and any binding molecule could be expressed by filamentous phage within certain structural limitations of the signaling sequence. The claimed invention states that the binding molecule has a "desired specificity" for the target. However, the claimed invention does not include any structural information regarding how the binding molecule binds the target or a binding affinity range that would be considered "desirable specificity". In addition, the claimed invention does not include any structural information regarding how a binding molecule is surface displayed on a filamentous bacteriophage (e.g. which structures can surface display, minimum sequence requirements of the structures, size

limitations of the insert, if the naturally occurring structure of the binding molecule can be displayed, if the surface display molecule alters the structure of the binding molecule, etc.).

The specification teaches that gIII and gVIII can be utilized the nucleic acids which direct surface display and M13 and fd as the filamentous bacteriophage (the specification also provides a "laundry list" of other bacteriophage – please refer to MPEP § 2163.05). In addition, the specification also teaches surface display of the following "binding molecules": Fv, V_H, pAb, alkaline phsphatase, PDGF, nuclease, and CD4 (the specification also provides several generic "binding molecules" including IgG, hormones, receptors, enzymes, and antibodies) and various targets including the generic targets of receptors, ligands, analogues, substrates, or antigens. Please refer to the entire specification particularly the Examples provided. Furthermore, the specification does not teach how every known and every potential "binding molecules" of every size and structure can be surface displayed on every filamentous bacteriophage (e.g. would every transmembrane or extracellularly expressed protein on bacteriophage be conducive to express every "binding molecule" on the surface?). Therefore, one skilled in the relevant art would not reasonably conclude that the Applicants had possession of the invention as claimed since the structural limitation of the nucleic acid necessary for surface display is not included in the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was *in possession of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons

of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See page 1116.).

With the exception of utilizing gIII or gVIII of M13 or fd filamentous bacteriophage to display Fv, V_H, pAb, alkaline phosphatase, PDGF, nuclease, or CD4 as disclosed by the specification, the skilled artisan couldn't envision the method of claim 1. While applicants have disclosed working examples for surface display of various genera, adequate written description for the "supergenus" of potential "binding molecules" is not provided (e.g. binding molecule = supergenus, receptor = genus, antibody = subgenus, Fv specific for oestriol = species). Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class wherein the specification provided only the bovine sequence.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Ladner et al. U.S. Patent 5,223,409 earliest potential effective filing date of September 2, 1988.

For present claim 1, Ladner et al. teach methods of displaying binding proteins on the surface of filamentous bacteriophage via nucleic acid sequences including gIII and screening for target molecule binding (please refer to entire document particularly abstract; columns 1, 4-12, 15-105; Examples I-XVI; claims 1-66).

For present claim 2, Ladner et al. teach separating bacteriophage expressing binding proteins form the target molecules (please refer to entire document particularly columns 10-12, 93-98).

For present claim 3, Ladner et al. teach recovering of separated bacteriophage (please refer to entire document particularly columns 10-12, 98-99).

For present claim 4, Ladner et al. teach expressing the binding protein in another expression system including bacterial cells, spores, and artificial methods, etc. (please refer to entire document particularly columns 8, 10, 50-77).

For present claim 5, Ladner et al. teach utilizing the methods to express antibodies including the Fc portion (please refer to entire document particularly columns 15-16).

Therefore, the presently claimed invention is anticipated by the teachings of Ladner et al.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-5 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20, 23-24, 30-40, 43-49, and 52-57 of U.S. Patent No. 5,969,108. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed invention and the invention as claimed in U.S. 5,969,108 are drawn to methods of producing binding molecules or binding pair members surface displayed on filamentous bacteriophage and selecting or screening for binding to a target or complementary binding pair member.

For present claim 1, U.S. Patent 5,969,108 claims methods of producing a member of a specific binding pair (sbp) via expressing a component of a secreted filamentous bacteriophage so that the phage displays the sbp on the surface of the phage and selecting phage expressing the sbp by affinity with a member complementary to the sbp (please refer to claims 1-15, 18, 30-34, 37, 44-46, 49, and 52-53).

For present claims 2-3, U.S. Patent 5,969,108 claims elution of phage from the complementary member and recovering the phages (please refer to claims 16-17, 35-36).

For present claim 4, U.S. Patent 5,969,108 claims deriving or obtaining nucleic acid from the phage and expressing the sbp (please refer to claims 19-20, 23-24, 38-43, 47-48, 54-57).

For present claim 5, U.S. Patent 5,969,108 claims sbp comprising a binding domain of an antibody (e.g. an antibody comprises a Fc portion; please refer to claims 1-4).

Therefore, the claimed invention of U.S. Patent 5,969,108 is an obvious variation of the presently claimed invention.

14. Claims 1-5 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-41 of U.S. Patent No. 5,885,793. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed invention and the invention as claimed in U.S. Patent 5,885,793 are drawn to methods of producing or providing a binding molecule or a specific biding pair member expressed on the surface of a filamentous bacteriophage and selecting the bacteriophage which surfaces expresses a binding molecule or binding member that binds to a self antigen or a target.

For present claim 1, U.S. patent 5,885,793 claims providing a library of filamentous bacteriophage surface expressing a specific binding pair member (sbp) wherein the providing entails producing the filamentous bacteriophage surface expressing the sbp and selecting the sbp surface displaying bacteriophage that binds a self antigen (please refer to claims 1-14, 17-20, 29-32, 37-39, and 41).

For present claims 2-4, U.S. patent 5,885,793 claims isolation and recovery of nucleic acid from the filamentous bacteriophage and expression of the nucleic acid (please refer to claims 15, 21-28, 33-36, and 40).

For present claim 5, U.S. patent 5,885,793 claims Fc fragments (please refer to claims 18-19).

Therefore, the claimed invention of U.S. Patent 5,885,793 is an obvious variation of the presently claimed invention.

15. Claims 1-5 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,555,313. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed invention and the invention claimed in U.S. Patent 6,555,313 are drawn to methods of providing or producing members of a specific binding pair or a binding molecule surface displayed on filamentous bacteriophage wherein the providing comprises producing and selecting by binding with self antigen or a target.

For present claim 1, U.S. Patent 6,555,313 claim methods of obtaining a member of a specific binding pair (sbp) by providing a sbp surface displayed on filamentous bacteriophage and selecting by binding to a human self antigen (please refer to claims 1-15 and 18-22).

For present claims 2-4, U.S. Patent 6,555,313 claims isolation and recovery of nucleic acid form the bacteriophage and utilized for expression (please refer to claims 16-17).

For present claim 5, U.S. Patent 6,555,313 claims Fc fragments (please refer to claims 19-20).

Therefore, the claimed invention of U.S. Patent 6,555,313 is an obvious variation of the presently claimed invention.

16. Claims 1-5 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,582,915. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed invention and the invention as claimed in U.S. Patent 6,582,915 are drawn to

methods of producing or providing libraries of filamentous bacteriophage surface expressing a specific binding pair (sbp) or a binding molecule and selecting via binding to a target.

For present claim 1, U.S. Patent 6,582,915 claims methods of producing a sbp by providing a library of filamentous bacteriophage that surface display a sbp and selecting a spb surface displayed on the bacteriophage that binds to a target human self antigen (please refer to claims 1-4).

For present claims 2-4, U.S. Patent 6,582,915 claims obtaining nucleic acid form a filamentous bacteriophage and expressing the nucleic acid (please refer to claims 5-8).

For present claim 5, U.S. Patent 6,582,915 claims Fc tail (please refer to claim 9).

Therefore, the claimed invention of U.S. Patent 6,582,915 is an obvious variation of the presently claimed invention.

17. Please note that several other patents claiming methods of producing specific binding pair members or antibodies or dimers displayed on the surface of filamentous bacteriophage and screened or selected for binding to a target or a complementary binding pair member that have common inventors and/or common assignees were found. Thus claims 1, 2, 3, 4, and/or 5 are also rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent 5,871,907; claims 1-40 of U.S. Patent 5,858,657; claims 1-85 of U.S. Patent 5,837,242; claims 1-54 of U.S. Patent 7,063,943; claims 1-98 of U.S. Patent 6,916,605; claims 1-40 of U.S. Patent 6,521,404; claims 1-54 of U.S. Patent 6,544,731; and claims 1-8 of U.S. Patent 6,593,081. Additionally, if applicants are aware of any U.S. Patent

applications which are obvious variants of the presently claimed invention they are respectfully requested to notify the examiner of the pending U.S. applications.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ADS
September 27, 2006

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